K041290

MAY 2 4 2004

510(k) SUMMARY

Talia Technology, Ltd's
RTA Model D Retinal Thickness Analyzer

Contact Information:

Submitter: Talia Technology, Ltd.
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Contact Person: Mr. Efi Amoyal, QA Manager

Name of The Device: RTA Model D Retinal Thickness Analyzer

Common or Usual Name: Retinal Thickness Analyzer

Classification Name: Ophtalmoscope, AC-Powered (Product Code HLI)

Predicate Devices: Talia Technology Ltd.'s RTA Retinal Thickness Analyzer

Intended Use:

The RTA Model D Retinal Thickness Analyzer ("RTA Model D") is a computerized slitlamp biomicroscope that is intended to provide manual and computerized tomography of the retina *in vivo*. The RTA Model D scans successive slit images on the fundus, without the need for a contact lens, to determine the thickness and the inner structure of the retina, both by observation of the slit images and by computer analysis of these images. It is indicated for assessing the area and location of retinal thickness abnormalities, such as thickening due to macular edema and atrophy associated with degenerative diseases, and for visualizing other retinal pathologies.

Device Description, Principles of Operation, and Technological Characteristics:

The RTA Model D is a computerized electro-optical system comprised of two primary components, namely the optical head and the computer system. The main elements of the optical head include laser and conventional light sources, optics, a scanner, and a digital camera.

The RTA Model D is a computerized slitlamp biomicroscope that provides manual and computerized tomography of the retina *in vivo*. The RTA Model D scans successive slit images of the fundus to determine the thickness and the inner structure of the retina, both by observation of the slit images and by computer analysis of these images. The RTA Model D uses a solid-state laser source that emits green light at a wavelength of 532 nm. The beam is focused into a thin slit and, by means of a mirror, is directed toward the eye. The scanner and optics then detect the image of the illuminated portion of the retina and transmit the image to the digital camera. The digital camera then captures the image, where it can then be stored and analyzed by the computer system.

Substantial Equivalence:

The RTA Model D is a modification to the previously cleared RTA Retinal Thickness Analyzer. The only differences between the previously cleared RTA and the modified RTA Model D are:

1. The Laser source has been changed from a green He-Ne operating at 543nm to a green Solid State laser operating at 532nm;
2. The interference filter has been modified accordingly; and
3. The laser beam optics has been modified to account for a slightly different beam size.

Through design control assessment, including verification and validation testing, Talia has demonstrated that the modifications to the cleared RTA do not raise any new questions of safety or effectiveness. Accordingly, the RTA Model D is substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 2 4 2004

Talia Technology Ltd.
c/o Jonathan S. Kahan
Hogan & Hartson L.L.P.
555 Thirteenth St. N.W.
Washington, DC 20004-1109

Re: K041290
Trade/Device Name: RTA Model D Retinal Thickness Analyzer
Regulation Number: 21 CFR 886.1570
Regulation Name: Ophthalmoscope, AC-Powered
Regulatory Class: Class II
Product Code: HLI
Dated: May 13, 2004
Received: May 13, 2004

Dear Mr. Kahan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4613. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

ATTACHMENT 7

Indications For Use Statement

510(K) Number (if known): _____

Device Name: RTA Model D Retinal Thickness Analyzer

Indications for Use:

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Prescription Use __X__ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ✓ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Denis L. McCarthy

(Division Sign-Off)
Division of Ophthalmic Ear, Nose and Throat Devises

510(k) Number K041290